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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/478,748	06/07/95	WALDMANN	T 2026-4003US3

EXAMINER	
GAMBEL, P.	
ART UNIT	PAPER NUMBER
1644	27

HM12/1217

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DATE MAILED: 12/17/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 10/5/99

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 27 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 27 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1998-404-496/40517

DETAILED ACTION

1. Applicant's amendment, filed 10/5/99 (Paper No. 26), is acknowledged.

Claims 1-23 have been canceled previously.
Claim 27 is pending and being acted upon presently.

2. The text of those sections of Title 35 USC not included in this Action can be found in prior Actions.
This Office Action will be in response to applicant's arguments, filed 10/5/99 (Paper No. 26).
The rejections of record can be found in the previous Office Actions (Paper Nos. 7/9/12/17/20/25).

3. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84.
Please see form PTO-948 previously sent in Paper No. 7.
Applicant is reminded to change the Brief Description of the Drawings in accordance with these changes (see 7. Views).

4. The priority date of the instant claimed limitations appears to be that of the instant application (6/7/95).

5. Claim 27 stands rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious Waldmann (Blood, 1993). Waldmann et al. teaches treating patients with yttrium-labeled anti-Tac antibody in the dosages ranges including the determination of soluble IL-2R levels, encompassed by the claimed methods (see entire document, including Materials and Methods such as the Therapeutic Study Plan, Results including Tables 1 and 2, Discussion). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced therapeutic modalities.

In the alternative, it would have obvious to give 20 mg of anti-Tac comprising 5-15 mCi ytrrium to patients with sIL-2R levels of greater than 50,000 given the clinical results/duration of the different patients in these studies. From the teachings of the reference, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments, filed 10/5/99 (Paper No. 26), including applicant's arguments and the Waldmann declaration under 37 C.F.R. § 1.132 filed 3/2/99 (Paper Nos. 23/24) have been fully considered but are not found convincing in that Waldmann (Blood, 1993) appears to teach treating patients with yttrium-labeled anti-Tac antibody in the dosages ranges including the determination of soluble IL-2R levels, encompassed by the claimed methods.

Applicant argues that Waldmann et al. Does not teach using radiolabeled antibody. However, page 1711, column 1, paragraph 1 clearly indicates the use of 5-15 mCi doses of ^{90}Y anti-Tac antibody treatment of 10-15 patients with ATL wis invited to distinguish this reference from the instant claimed method.

Although applicant argues that the claimed methods provide for different dosages for patients of differs sIL-2R levels; applicant has not provided sufficient objective evidence that would distinguish the amount of anti-Tac antibody, including ^{90}Y anti-Tac antibody in ATL patients, as taught by the prior art.

Although applicant argues that the prior art does teach each and every element of the claim; all that is required of the prior art is to meet the claimed methods. A species will anticipate a claim to a genus. See MPEP 2131.02. Applicant's claimed methods recite various levels of ^{90}Y anti-Tac antibody based in patients having different sIL-2R levels. The prior art does not have to meet each asserted level, provided it meets one of the ranges of ^{90}Y anti-Tac antibody / sIL-2R levels.

Applicant's arguments are not found persuasive.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Patent Examiner
Technology Center 1600
December 13, 1999

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SUPERVISORY PATENT EXAMINER
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